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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

ALKERMES, INC. and ALKERMES  
PHARMA IRELAND LIMITED,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

Civil Action No. 20-12470 (MCA)(MAH)

(Filed Electronically)

**BENCH MEMO IN SUPPORT OF OBJECTIONS TO TEVA'S USE OF  
PTAB'S INSTITUTION DECISION**

**TABLE OF CONTENTS**

	<b>Page</b>
INTRODUCTION .....	1
I. Courts Have Exercised Discretion to Exclude Post-Grant Review Decisions by the Patent Office .....	2
II. Teva’s Experts Did Not Rely on the Institution Decision, and It is Unfairly Prejudicial to Cross Alkermes’s Experts With the Decision .....	3
III. The PTAB Institution Decision Applied Procedural and Substantive Legal Standards Different from Those Applicable to Teva’s Defenses at Trial.....	3
IV. The Institution Decision is Irrelevant and Inadmissible Because the Underlying Record is Different and Contains Inadmissible Hearsay .....	4
CONCLUSION.....	5

**TABLE OF AUTHORITIES**

**FEDERAL CASES**

*ART+COM Innovationpool GmbH v. Google Inc.*,  
No. 14-217, 2016 WL 11531119 (D. Del. May 16, 2016) .....2

*Belden Tech. Inc. v. Superior Essex Comm’s LP*,  
802 F. Supp. 2d 555 (D. Del. 2011).....2

*Callaway Golf Co. v. Acushnet Co.*,  
576 F.3d 1331 (Fed. Cir. 2009).....2

*Coleman v. Home Depot, Inc.*,  
306 F.3d 1333 (3d Cir. 2002).....5

*Interdigital Comm’s Inc. v. Nokia Corp.*,  
No. 13-10-RGA, 2014 WL 8104167 (D. Del. Sept. 19, 2014).....2

*Microsoft Corp. v. i4i Ltd. P’ship*,  
564 U.S. 91 (2011).....3, 4

*Phillips v. AWH Corp.*,  
415 F.3d 1303 (Fed. Cir. 2005) .....4

*Server Tech., Inc. v. American Power Conversion Corp.*,  
No. 3:06-CV-00698–LRH, 2014 WL 1308617 (D. Nev. Mar. 31, 2014) .....2, 4

*Shire Dev. LLC v. Amneal Pharm. LLC*,  
No. 15-2865, 2016 U.S. Dist. LEXIS 100644 (D.N.J. Aug. 2, 2016) .....2, 4

*SSL Services, LLC v. Citrix Sys., Inc.*,  
769 F.3d 1073 (Fed. Cir. 2014).....2

**FEDERAL STATUTES**

37 C.F.R. § 42.100(b) .....4

35 U.S.C.  
§ 282(a) .....3  
§ 316(e) .....4

Fed. R. Evid.  
R. 403 .....2, 4  
R. 801(c) .....4  
R. 803(8)(C) .....5  
R. 805 .....5

**TABLE OF ABBREVIATIONS**

Alkermes or Plaintiffs	Plaintiffs Alkermes, Inc. and Alkermes Pharma Ireland Limited
Amneal	Third Party Amneal Pharmaceuticals LLC
“institution decision” or “Inst. Dec.”	<i>Amneal Pharm. LLC v. Alkermes Pharma Ireland Ltd.</i> , IPR2018-00943, Paper No. 7 (P.T.A.B. Nov. 7, 2018)
IPR	<i>Inter partes</i> review
Patent-in-Suit or '499 Patent	U.S. Patent No. 7,919,499 to E. Ehrich, PTX-1
POSA	Person of ordinary skill in the art
PTAB	Patent Trial and Appeal Board at the PTO
PTO	U.S. Patent and Trademark Office
Teva	Defendant Teva Pharmaceuticals USA, Inc.

## INTRODUCTION

Alkermes objects to Teva's attempt to use at trial a PTAB's decision to institute (*i.e.*, commence) an IPR proceeding to advance Teva's defenses of patent invalidity.<sup>1</sup> Although the PTAB institution decision is located in the file history for the '499 patent,<sup>2</sup> the content of that decision cannot be used by Teva at this trial. None of Teva's experts cited to or relied on the PTAB institution decision or its underlying record in their reports, and none of them discussed it during Teva's case in chief. And, because Teva's experts did not address the institution decision in their reports, it is unfairly prejudicial to suggest that Alkermes's experts should have relied on it when responding to them. The reasons Teva's experts did not rely on the decision, and the reasons it is irrelevant to Teva's defenses here, are clear:

- The institution decision was a preliminary decision to commence administrative proceedings, made on a non-final, incomplete record. This record is fundamentally different from a full trial record and includes hearsay declarations from different experts for a different patent challenger who were not subject to deposition or cross-examination.
- The PTAB applied lesser procedural and substantive legal standards than those the patent statute, Supreme Court, and Federal Circuit require a district court to apply.

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<sup>1</sup> The IPR petition was filed by a non-party, Amneal, on April 20, 2018. The PTAB institution decision explains a rationale for allowing the administrative proceeding to commence based on a limited record and special rules for reviewing that record. After the institution decision at issue here, the parties engaged in further proceedings and the matter settled. Accordingly, no final PTAB ruling on the merits was reached. The only PTAB decision Teva is seeking to use is that initial commencement ruling.

<sup>2</sup> Teva focuses on the point that the institution decision is in the file history, which is of record in this case and listed on the parties' exhibit lists. The record underlying that decision, however, is *not* in the file history and was not otherwise included in the final pretrial order. To be clear, Alkermes's objection, as explained herein, is not to the institution decision document itself, but Teva's improper *use* of it at trial or consideration of that decision to decide this case on a different record under different legal standards.

# **I. Courts Have Exercised Discretion to Exclude Post-Grant Review Decisions by the Patent Office**

Courts have properly exercised discretion to refuse to consider preliminary IPR decisions. *See, e.g., Interdigital Comm's Inc. v. Nokia Corp.*, No. 13–10–RGA, 2014 WL 8104167, at \*1 (D. Del. Sept. 19, 2014) (excluding an IPR denial under Fed. R. Evid. 403 because of the reasonable likelihood standard, IPR decisions are not made by POSAs, and the defendant was not a party in the IPR); *ART+COM Innovationpool GmbH v. Google Inc.*, No. 14-217, 2016 WL 11531119, at \*2 (D. Del. May 16, 2016) (excluding evidence from an IPR under Fed. R. Evid. 403 because the record was not complete and there was no full adversarial proceeding); *Shire Dev. LLC v. Amneal Pharm. LLC*, No. 15-2865, 2016 U.S. Dist. LEXIS 100644, \*9 n.3 (D.N.J. Aug. 2, 2016) (finding that an IPR claim construction decision has no probative value for the district court's claim construction because of the different legal standards and parameters).

This is consistent with other court decisions refusing to consider patent office decisions rendered on different records and different legal standards. *See, e.g., SSL Services, LLC v. Citrix Sys., Inc.*, 769 F.3d 1073, 1092-93 (Fed. Cir. 2014) (“the probative value of unfinished agency [reexamination] was substantially outweighed by the risk of unfair prejudice to the patentee and the potential for misleading the jury, thereby justifying exclusion under Federal Rule of Evidence 403.”); *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1342-43 (Fed. Cir. 2009) (affirming exclusion of evidence from an ongoing reexamination because of low probative value and high risk of confusion); *Belden Tech. Inc. v. Superior Essex Comm's LP*, 802 F.Supp.2d 555, 569 (D. Del. 2011) (excluding evidence of a reexamination); *Server Tech., Inc. v. American Power Conversion Corp.*, No. 3:06–CV–00698–LRH, 2014 WL 1308617, at \*4 (D. Nev. Mar. 31, 2014) (excluding evidence of a reexamination because it was not final, would be prejudicial, and has a different standard of proof and standard for claim construction).

The difference in the record and substantive and procedural legal standards is further discussed below.

## **II. Teva's Experts Did Not Rely on the Institution Decision, and It is Unfairly Prejudicial to Cross Alkermes's Experts With the Decision**

Teva bears the burden of proving invalidity by clear and convincing evidence. With that affirmative burden of proof, Teva's experts proffered hundreds of pages of expert reports offering myriad opinions, only some of which Teva is advancing at trial. None of their reports referred to the PTAB institution decision. Alkermes's experts then responded to those reports. D.I. 100. Teva will likely seek to cross Alkermes's experts with the PTAB institution decision.<sup>3</sup> But for Teva to confront Alkermes's experts with this decision when Teva did not believe it was consequential enough for its own experts to address it is disingenuous and unfairly prejudicial. Teva may be using the cross as an opportunity to bring out counsel arguments (as it did in its opening), but those arguments are improper for cross-examination and, for the reasons discussed below, they should not be part of this record.

## **III. The PTAB Institution Decision Applied Procedural and Substantive Legal Standards Different from Those Applicable to Teva's Defenses at Trial**

The patent statute and Supreme Court and Federal Circuit rulings set out the legal standards for this litigation, including that Teva must prove its invalidity defenses by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91 (2011); 35 U.S.C. 282(a). By contrast, the PTAB decided to commence an IPR based on several different legal standards that are fundamentally different (and less stringent) from those applicable in this trial, including:

(1) In deciding whether or not to institute, the PTAB viewed genuine issues of material fact in a light most favorable to the patent challenger. DTX 002.0801.

(2) The PTAB applied a standard of reasonable probability of proving unpatentability by a

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<sup>3</sup> In repeated meet-and-confers, Teva refused to state it would not do this.

preponderance of the evidence, not the clear and convincing evidence standard. *Compare* 35 U.S.C. § 316(e) *with Microsoft Corp.*, 564 U.S. at 97.

(3) At that time, the PTAB construed claims under a “broadest reasonable interpretation” standard different from *Phillips*<sup>4</sup> (the PTAB has since repudiated this standard). *Compare* DTX 002.0784 *with* 37 C.F.R. § 42.100(b) (2023).

For this reason it would be legal error to consider the PTAB commentary on that record in the present case. *Server Tech., Inc.*, 2014 WL 1308617, at \*4; *see also Shire*, 2016 U.S. Dist. LEXIS 100644, at \*9 n.3.

Further, even if it were relevant (it is not), Teva’s reliance on the decision should be prohibited under Fed. R. Evid. 403 because it creates confusion and unfair prejudice. Alkermes should not have to address the institution decision and try to explain it, its different arguments, incomplete record, and hearsay declarations, without that underlying record having even been addressed by Teva’s experts or included in the final pretrial order. And for the Court to rely on that decision, even inadvertently, in deciding this case on the present record and applicable law, would be unfairly prejudicial and would create legal error.

#### **IV. The Institution Decision is Irrelevant and Inadmissible Because the Underlying Record is Different and Contains Inadmissible Hearsay**

Teva’s experts did not cite, and Teva did not include in the final pretrial order, the underlying record on which the institution was based. That underlying record, relied on in the PTAB decision itself, included statements from the declaration of an expert witness for the patent challenger. PTAB procedure offered no opportunity for that expert to be deposed or cross-examined before the institution decision, and he is not a witness in the present case. His opinions and statements are pure hearsay here. Fed. R. Evid. 801(c). They, and the PTAB ruling relying

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<sup>4</sup> *Phillips* requires that claim terms be construed based on their ordinary meaning as understood from the use of those terms in the intrinsic evidence and that any extrinsic evidence be consistent. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*).



on such out of court statements, are not admissible under the Rule 803(8)(C) public records exception. For example, the institution here is not trustworthy because it is a non-final decision that relied heavily on hearsay supplied by a party with an interest in the outcome of the IPR and applied different legal standards to a different record. *See, e.g., Coleman v. Home Depot, Inc.*, 306 F.3d 1333, 1342 n.4 (3d Cir. 2002) (in evaluating whether an administrative agency’s findings are trustworthy, courts shall consider (1) the finality of the agency findings and (2) whether the agency findings are based on otherwise inadmissible evidence or materials offered by a party with an interest in the outcome of the proceeding). Moreover, even if the decision were admissible, the hearsay within it is not. Fed. R. Evid. 805. Accordingly, the institution decision is inadmissible for this additional reason.

Moreover, during its opening, Teva sought to argue that the PTAB decision construed “parenterally administering a long-acting formulation comprising about 310 mg to about 480 mg of naltrexone . . . .” But in the claim construction section of the institution decision, the PTAB did not even engage in a claim construction analysis for that particular claim term (which would have been under a different standard anyway). To try to use that preliminary decision to bypass the court’s obligation to perform a proper claim construction process based on the plain meaning apparent in the patent claims, specification, and prosecution history underlying the grant of the patent is plain legal error.

### **CONCLUSION**

For the foregoing reasons, Alkermes respectfully requests that Teva be precluded from using the institution decision at trial for any purpose.

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